

## REMARKS

### Claim Amendments

Claims 1, 8, 10, 11, 12 and 13 have been canceled. Claims 14-27 are withdrawn.

Claim 2 has been amended to include the feature of being "self-crosslinkable" and to clarify the molecular weight of the poly(caprolactone). The self-crosslinkable feature of the present invention provides for crosslinking in the absence of a crosslinking agent. This aspect is disclosed in the present specification in numerous places, for example: the Title, the Abstract, in the Specification on pages 2-3, paragraphs [0013], [0014], [0017], [0025] [0027]-[0030], etc. Claims 3-7 and 9 depend directly or indirectly from claim 2. The following remarks in response to the art rejections are respectfully provided to clarify the subject matter claimed by the present invention and to patentably distinguish the claims from the cited references.

### Art Rejections

Claim 2 was rejected under 35 USC 102(b) as being anticipated by Wiggins, "Design of bioabsorbable, amorphous polymer networks and composites" ("Wiggins"). Wiggins has prepared poly(D, L-lactide-co-[epsilon]-caprolactone) fumarate. The transitional phrase "consisting essentially of" in amended claim 2 excludes lactide groups as in Wiggins. Claim 2 clearly does not claim the lactide groups of Wiggins.

In addition, the lactide groups of Wiggins may adversely affect the softening temperature of a polymer. See page 3, lines 23-25 of the present

specification. In fact, Wiggins itself teaches in the Abstract that “[n]etworks synthesized from D, L-lactide based precursors were more rigid with higher tensile strengths and moduli, while networks synthesized from [epsilon]-caprolactone were more flexible and elastomeric.” The lactides in Wiggins teach away from the present invention.

Also, Wiggins does not teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention. It is submitted that the rejection under Wiggins has been overcome by the amendments to claim 2.

Claims 2 and 9 were rejected under 35 USC 102(b) as being anticipated by Chung *et al.*, European Polymer Journal, 39, 1817-1822 ("Chung"). Chung has prepared polycaprolactone trimethacrylate di(propylene fumarate)-dimethacrylate (PCL900TMA/DPFDMA). The two materials disclosed in Chung, namely: 1) di(propylene fumarate)-dimethacrylate (DPFDMA); and 2) polycaprolactone trimethacrylate (PCLTMA), both include methacrylates. The transitional phrase "consisting essentially of" in amended claim 2 excludes methacrylate groups taught in Chung. Claim 2 simply does not claim the methacrylate groups of Chung. Also, the methacrylate groups of Chung may adversely affect the biodegradability of a polymer. Even the "small methacrylic fragments present in Chung's and Fisk's polymers" cited by the Examiner could possibly form polymethacrylates that may adversely affect the biodegradability of the polymer.

Also, Chung does not teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention. The interpenetrating network in Chung was

achieved by reacting two materials DPFDMA and PCLTMA. It is submitted that the rejection under Chung has been overcome by the amendments to claim 2.

Claim 9 is also submitted to be patentable over Chung in view of the amendments to claim 2 from which it depends.

Claim 2 was rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 4,082,816 to Fisk *et al.* ("Fisk"). Fisk has prepared a coating composition by "polymerizing a mixture of vinyl monomers, including at least one monomer containing a -COOH and/or -OH functional group, with  $\epsilon$ -caprolactone" (column 1, lines 65-68 of Fisk, underlining added). Throughout the Examples of Fisk either an acrylate or a methacrylate monomer is used. In contrast to Fisk, the present invention does not use an acrylate or a methacrylate monomer, but instead starts with a caprolactone macromer or oligomer of low molecular weights.

The transitional phrase "consisting essentially of" in amended claim 2 excludes the mixtures of vinyl monomers as in Fisk. The vinyl monomers of Fisk are plainly excluded by amended claim 2. As discussed above with respect to Chung, the acrylate or methacrylate groups of Fisk may adversely affect the biodegradability of the polymer.

Also, Fisk does not teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention. It is submitted that the rejection under Fisk has been overcome by the amendments to claim 2.

Claims 2-7 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,747,605 to Breant *et al.* ("Breant"). Breant has prepared

polymers in which the "polycaprolactones employed are of high molecular weights and of two types: Tone 767E supplied by Union Carbide Company, of melt index of 30 dg/min, measured at 190.degree. C. under a 2.16-kg load. Capa 680, supplied by Solvay Interlox, of molecular mass of 80,000...." (See column 6, lines 55-62 of Breant. Underlining added.) The Tone 767E poly caprolactone has a molecular mass of 43,000 (based on Peluso et al., *Journal of Biomedical Materials Research*, Part A, Volume 34, Issue 3, Pages 327 – 336). Claim 2 requires using a poly(caprolactone) having a molecular weight in the range of 500-10000 daltons. The molecular mass of 80,000 of the Capa 680 is clearly greater than the claimed range in claim 2, and the 43,000 of the Tone 767E is also far outside the claimed range of the present invention. The molecular weight recited in claim 2 is well below the polymers used in Breant.

Further, the Examiner's rejection of claim 2 in view of Breant based upon the assertion that Breant's polymer must inherently have similar molecular weight characteristics to the present invention is not supported by the disclosure in Breant. In fact, Breant directly contradicts the specific limits on the molecular weight range of 500-10000 daltons in claim 2 where Breant specifically states that the polycaprolactones employed are of high molecular weights. Also, the examples given above are specific proof of this fact.

In addition, the high molecular weight polymers used in Breant may increase viscosity and softening temperature above that suitable for tissue engineering applications.

Also, Breant does not teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention. It is submitted that the rejection under Breant has been overcome by the amendments to claim 2.

Claim 9 was rejected under 35 USC 103(a) as being unpatentable over Breant. Applicants maintain that the underlying product of claim 2 is patentable for the above reasons, so claim 9 which depends from claim 2 is also patentable.

Claim 9 was also rejected under 35 USC 103(a) as being unpatentable over Kweon, Biomaterials, 24 (2003) 801-808 ("Kweon") in combination with Chung. As detailed above, Chung fails to disclose a copolymer consisting essentially of caprolactone units and fumarate units as recited in amended claim 2. Kweon describes a polymer formed by reacting acryloyl chloride and polycaprolactone. In contrast, the present invention uses fumaryl chloride which contains unsaturated carbon-carbon double bonds that can be used for in situ cross-linking. The fumaryl chloride is copolymerized with biodegradable poly(caprolactone) macromer that has a flexible backbone such that the resulting copolymer may self-crosslink in the absence of a crosslinking agent.

Given the formula of acryloyl chloride in Kweon, it is believed that the reaction of Kweon will produce a copolymer with acrylate groups, not fumarate groups as in the present invention. Additionally, the biodegradability problems with acrylate groups were discussed above.

Also, neither Kweon and Chung teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention. It is submitted that Kweon fails to make up for the deficiencies of Chung and therefore, the rejection under Chung

and Kweon has been overcome by the amendments to claim 2. Applicants maintain that the underlying product of claim 2 is patentable for the above reasons, so claim 9 which depends from claim 2 is also patentable

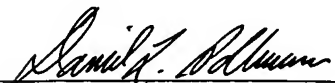
#### Chung Not Prior Art

In addition to the arguments made above, Applicants further respectfully submit that Chung is not prior art to the present invention. Chung was published in the European Polymer Journal, Volume 39, Issue 9 in September 2003. Applicants' maintain that their invention disclosure MMV-03-044 was completed and submitted no later than April 10, 2003 and possibly earlier. Applicants are prepared to provide proof in a Declaration under 37 CFR 1.131 to "swear behind" the Chung reference. For these reasons, Applicants respectfully submit that Chung does is not prior art and does not anticipate the claims of the present invention on its own or in combination with any other reference(s).

#### Conclusion

A fee of \$120 for a one-month extension of time (37 CFR 1.17(a)(1)) is believed to be needed for this amendment. A check for the same is enclosed along with a PTO/SB/22 Petition for Extension of Time under 37 CFR 1.136(a). If any refund is due, please submit a check to the undersigned.

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